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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/156,804 09/17/98 KALTENBACH

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022878 IM52/1010  
AGILENT TECHNOLOGIES, INC.  
INTELLECTUAL PROPERTY ADMINISTRATION, LE  
P.O. BOX 7599  
M/S DL429  
LOVELAND CO 80537-0599

EXAMINER

PEX, P ART UNIT	PAPER NUMBER
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1743  
DATE MAILED:

19  
10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/156,804

Applicant(s)

KALTENBACH ET AL.

Examiner

P. K. Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12, 25, 26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 25, 26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's addition of claims 28-30 is acknowledged and has been entered into the record.

#### *Drawings*

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "at least two separation units" and the "single reservoir adapted to contain a liquid for introduction through the inlet and into the micro-channel *of each separation unit*", as recited in claims 1, 25, and 28, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The current Figures show the reservoir unit 104 in connection to a *single* chip-shaped separation unit 102, not a plurality of separation units.

#### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-12, 25-26, 28-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1, introduces the new limitation of "at least two separation units". Each separation unit having a micro-channel, inlet and outlet. Additionally, "single reservoir unit..., adapted to contain a liquid for introducing through the inlet and into the micro-channel of each separation

unit, the reservoir having dimensions that enable successive operative and modular coupling to each separation unit". Examiner contends that a reservoir unit, which is simultaneously coupled to a plurality of separation units, <sup>was</sup> was not adequately disclosed within the instant specification. Applicant cites for support of this new recitation at page 3, line 19- page 4, line 2. This passage states that "a skilled person may choose a separation unit with a micro-channel of a particular length and size for the analysis of a particular sample and choose a separation unit with a micro-channel of different length and size for a different sample, but choose the same reservoir unit, power unit, heating unit, etc. for the analysis of both samples." This description does not support ~~the~~ structure of the apparatus as currently claimed. Additionally, Figures 1-2, 7B and 8, clearly indicate the use of a *single separation* unit connected to the reservoir unit. Examiner believes that applicant intended that the claim indicate an intended use which describes the reservoir unit as capable of modular coupling with a first single separation unit and whereupon completion of the analysis using the first single separation unit, this unit is discarded and a second separation unit is used by the same reservoir unit. This same reasoning is applicable to claims 25 and 28.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12, 25-26, 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4, the conditional phase " may be" is not a positive recitation, therefore, renders the claim indefinite. Same deficiency was found in claim 1, 25, 28.

Line 7, the phrase "adapted to" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. Same deficiency was found in claim 25.

Claim 28, line 9, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1, 3, 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyake *et al* (USP 5,519,635).

Miyake *et al* teach a apparatus for chemical analysis with multiple detachable separation units 11-13. The system of Miyake teach the coupling of a reservoir unit via connection 4 to the various separation units. This can be done either sequentially or in parallel (Fig. 1, 11). The separation unit comprising inlets and outlets and a plurality of channels (Fig. 2). The system

comprising a driving unit 52-55 for supplying or driving the liquid from reservoir to the micro-channel of each separation unit.

9. Claims 1, 3, 25 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Chow *et al* (USP 5,989,402).

Chow *et al* teach a micro-fluidic separation system comprising replaceable separation units 14. The separation units having inlets and outlets, and micro-fluidic channel. The system comprising a single reservoir unit having a plurality of reservoirs 24 containing a liquid and an external power unit coupled to a probe which applies a driving force from the reservoir to the micro-channel of the separation device. Additionally, the system comprising a support plate 206. The system further comprising a membrane or gasket placed on the surface of the reservoir unit (column 11, lines 15-20)

10. Claims 1-4, 6-9, 25-26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Sundberg *et al* (USP 6,090,251).

Sundberg *et al* teach a micro-fabricated structure for facilitating the introduction of fluids

into a micro-fluidic device. The system comprising a reservoir unit 32, 42 and a plurality of interchangeable separation devices 44. The separation devices having an inlet and outlet and channels 18 formed therein. The separation devices are chip-shaped and are formed from a first and second half wherein at least one of the surfaces has a planar surface that forms the micro-channel. Additionally, the system of Sundberg *et al* teach the use of an external power unit 52 for driving the liquid from the reservoir through the reservoir unit and into the micro-channel of the separation device via electrodes 54 (column 5, line 30- column 8, line 38).

11. Claims 1, 3, 25 and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Loux *et al* (WO 97/44132).

Loux *et al* teach a modular housing assembly for micro-machined fluid handling structure

comprising the use of a plurality of separation units 22 (page 11, lines 2- 16), each having micro-channels (not shown) ,inlet and outlet ports 60, 62, 64. Loux *et al* teach a single reservoir unit 24 comprising a plurality of reservoirs which introduce liquid into the inlet of the separation chamber via tubes, i.e., 51 which communicates with the interior channels of the separation unit 22. The system having pins 34, 36 and a clamp 48, such that the assembly is easily disassembled with the reservoir plate being easily separated from the micro-machined separation unit 22.

Additionally, the system comprises a modular heater 14 assembly. The reservoir unit having a membrane or seals captured between the reservoir plate and the separation unit to prevent leakage of the fluid. The system includes a power unit connected to the reservoir unit to supply pneumatic pressure to the reservoirs (Figs. 2, 5).

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 2, 4-9, 26, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake *et al* (USP 5,519,635) or Loux *et al* (WO 97/44132), in view of Swedberg *et al* . (USP 5,571,410).

Miyake *et al* or Loux *et al* (WO 97/44132) as previously discussed above, do not disclose wherein the separation unit is formed from a planar first an second half, wherein at least one of the halves has the channel formed thereon. Swedberg teaches a separation unit 2 having a planar first an second half, wherein at least one of the halves has the micro-channel 10 formed thereon (Figs. 4-17C).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in either systems of Miyake *et al* or Loux *et al* the separation unit, as taught by Swedberg, in order to derive a sample processing compartment featuring enhanced symmetry and axial alignment (column 5, lines 31-36).

15. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake *et al* (USP 5,519,635) or Loux *et al* (WO 97/44132) in view of Swedberg *et al* . (USP 5,571,410) as applied to claim 26, and further in view of Kaltenbach *et al* . (USP 5,641,400).

Miyake *et al* or Loux and Swedberg as disclosed above, do not teach an apparatus comprising a peltier plate operatively and modularly coupled to the support plate for controlling the temperature thereof. However, Kaltenbach does teach peltier plates for coupling to the



support plate for controlling the temperature thereof (column 20 lines 37-67 and column 21 lines 1-37, Figures 9A-10B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Miyake *et al* or Loux *et al* and Swedberg, peltier plates coupled to the support plate, in order to influence many of the physical and chemical parameters involved in separation techniques and decrease the time needed to perform the separation. The temperature can affect the sample stability, buffer viscosity, chemical equilibria, pH and the resulting migration time for a given chemical species (column 3 lines 9-21).

#### ***Response to Arguments***

16. Applicant's arguments with respect to claims 1-12 and 25-26, 28-30 have been considered but are moot in view of the new ground(s) of rejection. See above Office Action.

#### ***Conclusion***

17. No claims allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays from 6:00 am to 3:30 pm EST.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.



P. Kathryn Bex  
Patent Examiner  
AU 1743  
10/8/01

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700